



Attorney's Docket No.: 17080-002002 / 601B

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : McDonald *et.al* Art Unit : 1647
Serial No. : 09/360,242 Examiner : Landsman, R.
Filed : July 22, 1999 Cust. No. : 20985
Conf. No. : 3887
Title : *METHODS AND COMPOSITIONS FOR TREATING SECONDARY TISSUE
DAMAGE AND OTHER INFLAMMATORY CONDITIONS AND DISORDERS*

Mail Stop: Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith is a Petition pursuant to 37 C.F.R. §1.181 requesting withdrawal of the Final Office Action, mailed March 7, 2005, in connection with the above captioned application.

- [X] The Commissioner is hereby authorized to charge the fee for the Petition as well any fee due in connection with this application that may be due in connection with this and the attached papers, or with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie L. Seidman
Reg. No. 33,779

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CERTIFICATE OF MAILING BY "First Class Mail"

Date of Deposit: June 7, 2005
I hereby certify that this paper and the attached papers are being deposited with the United States Postal Service as first class (priority) mail on the date indicated above and is addressed to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie L. Seidman

The Examiner states at page 7 of the Office Action that:

This is a CONTINUATION of applicant's earlier Application No. 09/360,242. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). [Emphasis in the original.]

Specifically, claims 26-29, 31, 32, 35-37, 40, 42, 44-46, 48-54, 57 and 65-95 remain rejected and new claims 96 and 97 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to enable the full scope of the claims. Even though the rejection of the claims is maintained as a scope of enablement rejection, the Examiner has based this rejection, at least in part, on a new ground not previously presented. This new ground of rejection is not necessitated by amendment. The Examiner states in the third full paragraph of page 4 of the Office Action, that:

Furthermore, due to the scope of "targeted agent," which reads on more than toxins, it can be easily seen how a lack of guidance and working examples of these "agents" can be extrapolated to these "non-toxin" agents. Applicants have provided only minimal guidance and working examples of how to produce a toxin which has minimal side effects and no guidance or examples of agents other than toxins. However, the claims are not limited to this specific example. The level of the skill in the art is high and it would not be a simple matter to create a toxin which can still act as a toxin in a limited fashion – by affecting one group of cells without affecting another, as evidenced by the prior art.

It is respectfully submitted that this paragraph sets forth a new ground of rejection of the scope of the claims by urging that "targeted agent" "reads "on more than toxins" so that the claims are broader than the enabling disclosure.

The pending claims were not amended with respect to the scope of "the targeted agent." For example, claim 29, which is rejected on this basis was amended in the previous response as follows:

29. (Currently Amended) A method for ~~treating pathological conditions by treating the underlying pathology associated with inflammatory responses and secondary tissue damage associated with activation, proliferation and migration of immune effector cells~~ by inhibiting activation, proliferation or migration of immune effector cells, comprising administering a conjugate to an animal whereby activation, proliferation, migration of the immune effector cells is inhibited, wherein:

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the conjugate comprises a targeted agent or a portion thereof and a chemokine receptor targeting agent or a portion thereof sufficient to bind to a chemokine receptor on immune effector cells and facilitate internalization of the conjugate;

the chemokine receptor targeting agent is a chemokine, an antibody that specifically binds to a chemokine receptor or a fragment of the chemokine or antibody, wherein the chemokine, antibody or fragment thereof binds to the receptor and internalizes the targeted agent in a cell;

the targeted agent or portion thereof, when internalized in a cell, alters metabolism or gene expression in the cell, regulates or alters protein synthesis in the cell, inhibits proliferation of the cell or kills the cell; and

the conjugate binds to a chemokine receptor resulting in internalization of the targeted agent in cells bearing the receptor.

Only the preamble, which is not directed to the targeted agent was amended. The language "targeted agent" was not amended. In fact, this language has been recited in the claims throughout the prosecution history of this case, including in the original claims (see, *e.g.*, original claim 1, which is directed to a conjugate comprising a "targeted agent"). As another example, claim 35, which is subject to this rejection, was not amended in the previous response.

No ground of rejection based regarding the scope of the "targeted agent" was presented in the prior Office Action nor in any of the Office Actions in the file history of this application, nor is such rejection based upon information provided in an Information Disclosure Statement. Applicant has never had an opportunity to consider or to address this issue. If the finality of this Action is maintained, Applicant will not have such opportunity.

Thus, the present Office Action sets forth a new ground of rejection that is not necessitated by amendment nor based on information submitted in an Information Disclosure Statement. Accordingly, withdrawal of the finality of the Office Action is respectfully requested.

The fee for the Petition should be charged to Deposit Account No. 06-1050. Any fees that may be due in connection with this paper or with this application may be charged to Deposit Account No. 06-1050.

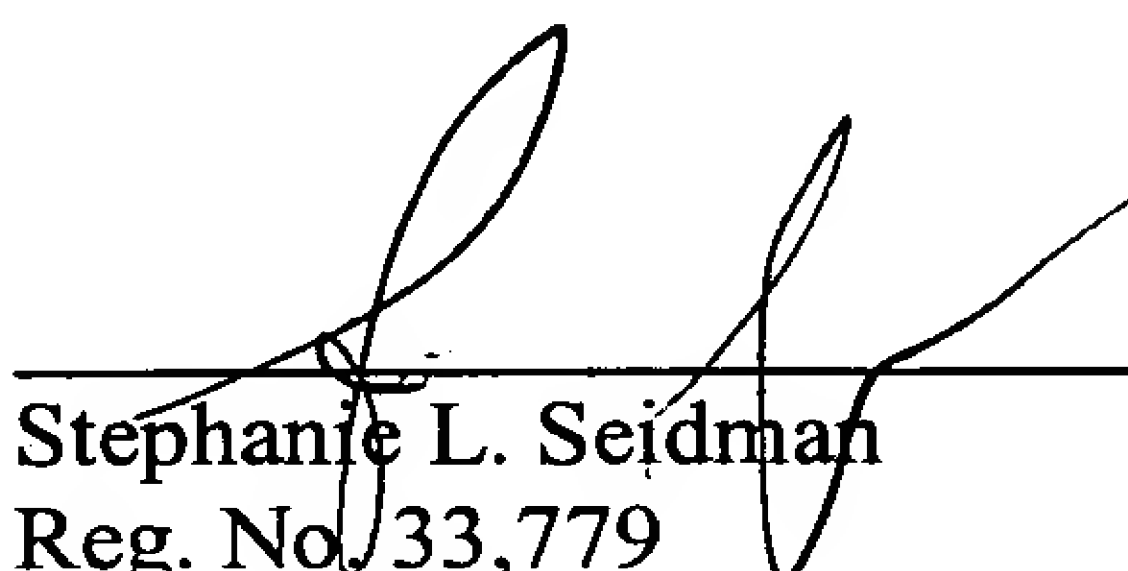
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In view of the above remarks, reconsideration and removal of the finality of the Office Action are respectfully requested.

Respectfully submitted,



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